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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,011 04/20/00 RANGANATHAN

N KBI-0003

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EXAMINER

PATTEN, P

ART UNIT

PAPER NUMBER

1651

12

DATE MAILED:

06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/557,011

Applicant(s)

Ranganathan et al.

Examiner
Patricia Patten

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/13/01 & 5/18/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

The request filed on 5/18/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/557,011 is acceptable and a CPA has been established. An action on the CPA follows.

The Amendment filed 4/13/01 was not entered initially because the new limitation 'wherein the sorbents possess a gut clearance rate for urea of at least 5.6 ml/min' would impart further consideration on the merits.

Claims 1-4 are pending in the application and were presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yatzidis et al. (1979) in view of Prakash et al. (1995) and further in view of Goldenhersh et al. (1976).

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Claim 1 recites a new limitation whereby the sorbents possess a gut clearance rate for urea of at least 5.6 ml/min.

Applicant's arguments filed 3/28/01 were considered, but were not found persuasive.

Applicants argue that the references, individually do not teach, nor provide the motivation to combine a mixture of sorbents known to absorb uremic toxins with a bacteria which metabolizes urea and ammonia in a microencapsulated form. Applicants further argue that the new limitation which recites 'wherein the sorbents possess a gut clearance rate for urea of at least 5.6ml/minute' is not taught by any of the prior art references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Because all of the instantly claimed ingredients were known in the art for treating uremia separately, one of ordinary skill in the art would have had a reasonable expectation that the combination of the ingredients would have provided an additive affect on the ailment of uremia. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to treat uremia. This rejection is based on the well established proposition of patent law that **no invention resides in combining old ingredients of known properties where the**

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results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Here, the Examiner is **relying upon case law in order to establish a prima facie case of obviousness**. Although the references themselves may not indicate a motivation to combine the Instantly claimed ingredients, the MPEP states 'The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; **the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (MPEP 2114).**

The new limitation which states that the sorbents possess a gut clearance rate for urea of at least 5.6 ml/min is merely an extrinsic property which does not materially change the composition. It would have been apparent to one of ordinary skill in the art that the mixture of sorbents along with a bacteria which metabolized urea and ammonia would have been optionally prepared in order to achieve the fastest possible uremic toxin absorbance. Because each respective sorbent inherently possessed specific absorption affinities for uremic toxins as displayed in the prior art, it would have been expected that a combination of sorbents would have had an additive effect with regard to absorption rates. Thus, varying the level of each sorbent material in the mixture would have merely been randomization of result effective variables, well known and routine in the art of pharmacology.

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No Claims are allowed.

This is a CPA of applicant's earlier Application No. 09/557,011. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

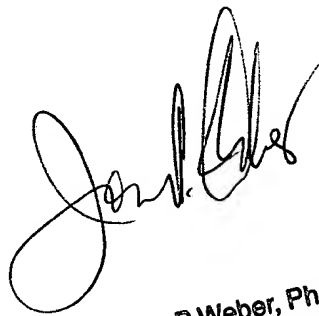
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber". The signature is stylized with a large loop at the beginning and a long, sweeping tail.

Jon P. Weber, Ph.D.
Primary Examiner